
State of Minnesota
In Court of Appeals

Alan and Keri Bearder, individually and as parents and
natural guardians of Josiah and Alexa Bearder, minors; et al.,
Appellants,

vs.

State of Minnesota,
Minnesota Department of Health,
and Dr. Sanne Magnan, Commissioner
of the Minnesota Department of Health,

Respondents.

APPELLANTS' BRIEF, ADDENDUM AND APPENDIX

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The appendix to this brief is not available for online viewing as specified in the *Minnesota Rules of Public Access to the Records of the Judicial Branch*, Rule 8, Subd. 2(e)(2).

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ISSUES

A. Whether Appellants stated a claim for damages and injunctive relief for Respondents' violation of the Genetic Privacy Act, Minn. Stat. § 13.386.

How Raised: Respondents raised this issue in their motion to dismiss and for summary judgment. (Def. Memo, pp. 16-27.)

District Court's Holding: The district held that Respondents did not violate the GPA.

How Preserved: Appellants preserved this issue through timely appeal of the district court's final judgment. (Appellants' Notice of Appeal, pp. 2-3; Appellants' Statement of the Case, p. 4.) No post trial motion was necessary to preserve this issue.

Apposite Authorities: *Pomeroy v. National City Co.*, 296 N.W. 513 (Minn. 1941) rehearing denied March 6, 1941; *Winters v. Duluth*, 84 N.W. 788 (Minn. 1901); Minn. Stat. §§ 13.386, 13.08, 144.125, 144.128, 645.16, 645.17; Minn. R. 4615.0300-.0700.

B. Whether Appellants' genetic material constitutes property, the taking of which requires just compensation under the Minnesota and United States Constitutions.

How Raised: Respondents raised this issue in their motion to dismiss and for summary judgment. (Def. Supp. Memo, pp. 26-29, 31.)

District Court's Holding: The district court held that this issue was "moot."

How Preserved: Appellants preserved this issue through timely appeal of the district court's final judgment. (Appellants' Notice of Appeal, pp. 2-3; Appellants' Statement of the Case, p. 5.) No post trial motion was necessary to preserve this issue.

Apposite Authorities: *The Board of Regents of State Colleges v. Roth*, 92 S. Ct. 2701 (1972); *Balkowitsch v. Minneapolis War Memorial Blood Bank, Inc.*, 132 N.W.2d 805 (Minn. 1965); *Green v. Commissioner of Internal Revenue*, 74 T.C. 1229 (T.C. 1980); *Carter v. Inter-Faith Hospital of Queens*, 304 N.Y.S.2d 97 (N.Y. Spec. Term 1969); U.S. Const., Amend. V; Minn. Const., Art. 1 § 13.

C. Whether Respondents' unlawful collection, storage, use and dissemination of Appellants' genetic material and genetic testing results gave rise to claims in tort.

How Raised: Respondents raised this issue in their motion to dismiss and for summary judgment. (Def. Supp. Memo, pp. 6-20.)

District Court's Holding: The district court held that this issue was "moot."

How Preserved: Appellants preserved this issue through timely appeal of the district court's final judgment. (Appellants' Notice of Appeal, pp. 2-3; Appellants' Statement of the Case, p. 5.) No post trial motion was necessary to preserve this issue.

Apposite Authorities: *Elli Lake v. Wal-Mart Stores, Inc.*, 582 N.W.2d 231 (Minn. 1998); *Balkowitsch v. Minneapolis War Memorial Blood Bank, Inc.*, 132 N.W.2d 805 (Minn. 1965); *Walsh v. Pagra Air Taxi, Inc.*, 282 N.W.2d 567 (Minn. 1979); *Bohdan v. Alltool Mfg., Co.*, 411 N.W.2d 902 (Minn. Ct. App. 1987) *review denied* Nov. 13, 1987; Minn. Stat. §§ 13.386, 13.08.

D. Whether Respondents' conduct violated Appellants' fundamental right to privacy and freedom from unlawful search under the Minnesota and United States Constitutions, whether Appellants are entitled to injunctive relief, and whether Appellants stated a claim damages under the Minnesota Constitution.

How Raised: Respondents raised this issue in their motion to dismiss and for summary judgment. (Def. Supp. Memo, pp. 23-25, 29-30.)

District Court's Holding: The district court held that this issue was "moot."

How Preserved: Appellants preserved this issue through timely appeal of the district court's final judgment. (Appellants' Notice of Appeal, pp. 2-3; Appellants' Statement of the Case, p. 5.) No post trial motion was necessary to preserve this issue.

Apposite Authorities: *Schmerber v. State of California*, 384 U.S. 979 (1966); *Skinner v. Railway Labor Executives' Association*, 481 U.S. 107 (1987); *State v. Gray*, 413 N.W.2d 107 (Minn. 1987); *In the Matter of the Welfare of C.T.L.*, 722 N.W.2d 484 (Minn. Ct. App. 2006); U.S. Const., Amend IV, X; Minn. Const., Article 1 §§ 8, 10, 16.

STATEMENT OF THE CASE

Respondents collect newborn blood samples at birth and test the samples for genetic disorders. Under the newborn screening statute, Respondents may keep a registry of positive test results, but are not authorized to keep anything more. Instead of destroying newborn blood samples and negative screening results when the testing was complete, Respondents began storing them in a DNA warehouse. As of December 31, 2008, the warehouse held over 1,500,000 screening records and over 800,000 newborn blood specimens of Minnesota children. Unbeknownst to the public at large, Respondents began sharing and selling the blood samples and screening results to private institutions for research. As of December 31, 2008, more than 50,000 blood samples had been used for research. Respondents did not obtain consent from a single parent for these activities.

Appellants brought this lawsuit seeking damages and injunctive relief for Respondents' unlawful collection, storage, use, and dissemination of their children's genetic material and genetic testing results without their consent. Respondents quickly moved to dismiss. The Hennepin County District Court, Judge Marilyn Brown Rosenbaum presiding, granted Respondents' motion. This appeal follows.

STATEMENT OF FACTS

Newborn Screening

In 1965, the Minnesota Department of Health (MDH) began testing all infants born in Minnesota for a single recessive genetic disorder. (AA, p. 210.) The process enlarged, until today where every infant is screened for more than 50 heritable and congenital disorders. (AA, p. 210.)

Newborn screening is governed by Minn. Stat. §§ 144.125, 144.128. Under the statutes, any institution caring for infants 28 days or less of age must arrange to have screening administered to every infant or child in its care. Minn. Stat. § 144.125, subdiv. 1. The statutes place this burden on the administrative officer or other person in charge of the facility, the person required to register the birth of the child, or the nurse midwife in attendance at the birth. Minn. Stat. § 144.125, subdiv. 1. The commissioner has a duty to “maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services.” Minn. Stat. § 144.128 (3). The Commissioner must notify physicians of newborn testing results and make referrals when treatment is indicated. Minn. Stat. § 144.128 (1)-(2).

Presently, a blood specimen is acquired from each Minnesota newborn child at the time of birth.¹ The specimen is dried blood, which is collected on a filter paper “specimen card.” (AA, p. 210.) The specimen card is provided to the “responsible

¹ If parents object to testing or elect to require that blood samples and test results be destroyed, the objection or election shall be recorded on a form that is signed by a parent and made part of the infant’s medical record. Minn. Stat. § 144.125, subdiv. 3. When the commissioner receives a destruction request, she must comply with the request within 45 days after receiving it and then must notify the individuals that the samples and test results have been destroyed. Minn. Stat. § 144.128 (5)-(6).

parties” by MDH. (AA, p. 210.) The specimens are analyzed at MDH’s laboratory and at Mayo Medical Laboratories. (AA, pp. 211-212.) Testing done at Mayo includes tests that check for the presence or absence of specific DNA or RNA markers. (AA, p. 212.)

In an executive decision, and without statutory authority, MDH began storing the left-over newborn blood samples on July 1, 1997. At this time, “MDH *indefinitely* stores any remaining blood spot material and test results...” (AA, p. 212, *see also* AA, pp. 179-180.) These stored samples and test results include personally identifiable information about the infants and their parents. (Def. Memo, p. 6.) MDH has blood samples dating back to 1997 and has records of test results dating back to the 1960s. (AA, p. 212.) MDH does not seek consent from the parents to retain the blood spots and test results. MDH instead provides “opt-out” information, in brochure form, to parents. (AA, p. 210.) The information is buried within a brochure (*See* AA, p. 222) and is often provided to parents during the “fog” of childbirth, and along with numerous other materials and forms provided to parents while in the hospital.

MDH has never sought written informed consent for the storage, use, or dissemination of the blood sample or test results after newborn screening is complete. Mark McCann (Manager of the Public Health Laboratory in the Newborn Screening Program) testified in legislative hearings: “[T]he number of parents who have given consent to store the dried, the residual dried blood spots with the Minnesota Department of Health is *zero*.” (AA, pp. 141-142.) MDH requires that parents who wish to opt-out their child from the program execute a written destruction request. (AA, p. 211.) A child who reaches the age of majority, learns of the opt-out provision, and later decides to have

his or her specimen or test results destroyed can also file a destruction request. (AA, p. 211.)

Many of the stored blood samples are then used by MDH for public health studies, and given or sold to outside, private entities, termed “independent research organizations.” (AA, p. 212.) Presently, MDH has a contract with Mayo for the analysis of newborn blood specimens that exceeds \$6,000,000. (AA, p. 139.) MDH admits that this contract allows Mayo to keep dried blood samples for two years and to perform its own tests on them. (AA, p. 140.) MDH also admits that its contract allows Mayo to keep the blood samples for *at least* two years.² (AA, p. 140.) MDH further admits that Mayo is allowed to keep the testing results indefinitely. (AA, p. 141.) McCann also testified before the ALJ that while MDH believes there is a federal requirement to retain the test results for 2 years, MDH had no reason to require that blood specimens be stored for that long. (AA, p. 47.)

As of December 31, 2008, MDH had warehoused 1,567,133 records of results of newborn genetic screening, had more than 800,000 Minnesota children’s blood spots in storage. They had used more than 50,000 blood spots for research. (AA, pp. 4, 143-144.) MDH refuses to definitively answer whether it continues to conduct studies using blood spots from children that are *over* 2 years old. (AA, p. 145-146.)

In a 2005 e-mail exchange, David Orren, MDH’s chief legal counsel, explained his belief that newborn screening was not subject to *any* data privacy laws. (AA, p.128.) MDH’s position was that the blood specimens were “property” and not data. (AA, p.

² MDH also asserts that Mayo destroys all blood samples in its control after two years. (AA, p. 141.) Appellants have not had the opportunity to verify this assertion.

128.) Orren stated with regard to rules governing the privacy and handling of the newborn blood specimens: “*Basically, we could pretty much make up what we wanted to do.*” (AA, p. 128 (emphasis added).) MDH also took the position that it had property rights in the blood specimens that trumped federal rules for use of blood specimens in human subject research. (AA, p. 128.)

Respondents allege that the samples used in public health studies without an individual’s consent are not dangerous, as they are “de-identified.” (AA, p. 212.) Respondents describe de-identification as “a sample that is not accompanied by information that identifies the infant from whom the sample was obtained.” (AA, p. 212.) Despite MDH’s reassurances, it is not so clear what MDH means when they say that the blood samples and test data are “de-identified.” Respondents have stated in discovery responses that, “No documents exist showing MDH processes of de-identification and reidentification, nor is there any documentation about an “unidentified” standard or random identification keys.” (AA, p. 131.)

In fact, there is no set de-identification procedure and the process and standards for de-identification vary from project to project and are subject to subjective standards. For example, an e-mail exchange between MDH employees establishes that “de-identification” is an apparently subjective standard within MDH. (AA, p. 132.) As the e-mail explains, the U of M cancer research center wished to use data from the cancer surveillance system, the birth registry, and newborn screening blood spots. (AA, p. 132.) MDH employees were to combine the data sources. (AA, p. 132.) The U of M would then “receive a dataset that contains little potentially identifying information.” (AA, p. 132.) However, the e-mail continues:

The only remotely identifiable information that the PI will receive is zip code from the MCSS (time of diagnosis), zip code from mother's mailing address from the birth certificate, and the exact date of birth from both sources. The PI would not be able to use publicly available data sources to identify the child with these two data elements. (Although if he had access to our full birth certificate data base, *he could identify some children in sparsely populated zip codes.*)

(AA, p. 132 (emphasis added.) The Department official had "No concerns." (AA, p. 132.)

In another example, MDH intended to provide newborn blood specimens to a third-party research institution for "DNA extraction." (AA, pp. 149-152.) According to the application, the specimens would "be assigned a random identification key, known only to the MDH Newborn Screening Program." (AA, pp. 149-152.) According the application, "Identity of all subjects (study and control groups) will not be revealed to the researchers or anyone else outside the MDH at any point of the study and will remain anonymous." (AA, pp. 149-152.) However, MDH would be able to associate the results of private testing with its database of identifiable individuals.

2006 Legislative Report

In addressing the dangers of government-held DNA information, and at the request of the legislature, the Minnesota Department of Administration issued a report in January 2006 entitled, "A report on Genetic Information and How it is Currently Treated Under Minnesota Law." (AA, pp. 185-205.) The report discusses potential misuses of genetic screening, including denial of insurance applicants or employers avoiding prospective employees with predisposition for expensive diseases. (AA, p. 190.) The report also details how genetic information's use and dissemination can affect an entire family. (AA, p. 190.) Examples included implication of a sibling in a crime or an

inadvertent discovery during medical diagnostic testing that a child is not biologically related to the parent. (AA, p. 190.) The study states, “*Genetic information is a powerful tool that can both assist and do harm. As a result, its collection, uses and disseminations should be controlled.*” (AA, p. 190 (emphasis added).)

The Genetic Privacy Act (GPA)

Following the report, the legislature adopted the Genetic Privacy Act. The act prohibits the collection, use, storage, and dissemination of “genetic information” without written, informed consent. Minn. Stat. § 13.386. If the government or a responsible authority violates the GPA, they are subject to a number of civil remedies. Minn. Stat. § 13.08, subdivs. 1, 2, 4.

Proposed 2007 Rule Changes & The ALJ Report

Following enactment of the GPA, MDH proposed new rules for newborn screening, that would avoid complying with the GPA, and avoid obtaining parental consent. (AA, p. 19.) Following a hearing on the proposed rule changes, the ALJ issued her findings of fact and conclusions. (AA, p. 17.)

The ALJ specifically found that MDH was avoiding informing Minnesota parents:

Based upon the information provided during this rulemaking proceedings, it appears that ***parents are not informed*** that the Department will maintain the test results for an indefinite period of time; that the parents may decide later to request that the blood sample and test results be destroyed; or that the blood sample may be provided to outside institutions for research purposes.

(AA, p. 34 (emphasis added).) The ALJ further found that the MDH proposed opt-out provision, which includes warnings about MDH’s retention and storage policy, is not

provided to parents until *after* they decide whether or not to permit the child's information to be retained. (AA, p. 34.)

The ALJ concluded that the newborn screening statute *did not* authorize the indefinite retention and disseminating of the genetic information without consent:

Moreover, while Minn. Stat. § 144.128 specifies that the Commissioner's duties shall include "maintain[ing] a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services," this provision does not provide any support for the Department's current practice of making information obtained from newborn screening available to third parties for research purposes. *There is no express authorization in the newborn screening statute for the Department's current practice of retaining the information indefinitely without consent and permitting the information to be used without consent* for purposes other than the detection, treatment, and follow-up of heritable and congenital disorders as contemplated by the newborn screening statute.

(AA, p. 38 (emphasis added).)

The ALJ found that the GPA "reflects a serious concern on the part of the Legislature about the collection and retention of genetic information..." (AA, p. 38.)

The ALJ further found:

[T]here is no basis for reading an implication into the statute that the Department is exempted from all of its provisions simply because a parent or guardian is given the option of opting out of the information retention system. In fact, if a parent or guardian elects not to opt out of the screening, the Department will retain the baby's genetic information for some period of time, ranging from 45 days to at least two years.

...
Therefore, after careful consideration, the Administrative Law Judge concludes that the newborn screening statute does not expressly authorize the Department to store genetic information indefinitely or disseminate that information to researchers without written informed consent provided by the parents.

(AA, p. 38 (emphasis in original).) The ALJ also found hospitals, physicians, and nurses acted as MDH's agents:

The proposed rules demonstrate that hospitals are merely acting, for a very brief period of time, as agents of the Department in carrying out the newborn screening program. ... It is the Department that collects and retains both the blood samples and the test results; the Department merely relies upon the responsible parties to implement the necessary communications and the actual drawing of blood.

(AA, p. 35.)

The ALJ ultimately concluded that the GPA applied to the proposed rules and the failure to incorporate the requirements of the GPA into the proposed rules constituted a defect. (AA, p. 38.) Because the ALJ concluded the proposed rules were defective, the report was submitted to the Chief Administrative Law Judge for his approval. (AA, p. 18.) The Chief Administrative Law Judge affirmed the ALJ's Report in all respects and further denied a request for reconsideration. (AA, pp. 56-57.) He explained:

The Department is relying on the *implication* that, because the parents have the option to have the blood spots destroyed in 24 months, a parent who does not elect that option is authorizing the Department to retain the blood spots indefinitely.

While one could reasonably draw that inference, Minn. Stat. § 13.386 requires more than a logical inference or implication. It requires the exception to its coverage to be "otherwise *expressly* provided by law."... An implication or logical inference is not an express provision. There is no express provision in law that exempts the blood spots from the coverage of Minn. Stat. § 13.386.

(AA, pp. 56-57 (emphasis in original).)

Recent Legislative Initiatives

Despite the ALJ's findings, MDH continued its practices. MDH has still not sought any type of consent for storing Minnesota children's blood specimens and test results. (AA, p. 134-136.) The commissioner did attempt in 2007, 2008, and 2009 to exempt the collection, storage, use, and dissemination of newborn blood from the GPA.

However, in 2008, Governor Tim Pawlenty vetoed a proposal providing for the opt-out system, specifically indicating to the MDH that he could not support a bill that exempting MDH from laws that required written, informed consent, like the GPA. (AA, pp. 58-59.) The legislature did not adopt any amendments to the GPA. (AA, p. 183.)

Legislative hearings on proposed amendments provide valuable insight into Respondents' conduct and the GPA's intent. Take this excerpt, for example:

Senator Hann:

And, Mr. Chairman and Mr. McCann, I guess I thought that was a requirement, that any collection or storage or use of genetic material had to – it was required that informed consent be a part of that process to do that, so I'm not sure if I understand why you say there's no law that governs that. I thought we did have a general law that said you can't store this without consent.

Mr. McCann:

Mr. Chair, Senator Hann, I don't think my response indicated *that there wasn't a law, just not a current practice for us to have written, informed consent to operate a newborn screening program (emphasis added)*.

Within the boundaries of program operations – our interpretation of current law – it's well within the boundaries to operate a program and use those dried blood spots to test and also for quality assurance, quality control, and quality improvement outcomes.

Senator Hann:

Well, Mr. Chairman and Mr. McCann, I really object to that. I – my understanding is the law on informed consent is pretty clear. It sounds like what you're saying is that you just have not been abiding the law and collecting and storing the material anyway.

...

And I find this disturbing that the Department has been acting in this fashion, when it seems to me to be pretty clear that you need to have informed consent if you're going to collect this kind of material from people and use it for any purpose, and I'm concerned that the Department has been ignoring that law or those provisions and now you have brought a law that is, in effect, giving you that statutory authority to do what you have been doing without authority.

...

What I'm objecting to is the Department retaining the material that they get from the screening for up to two years to use for purposes that they decide what those purposes may be without the informed consent of the patient or the – in this case, the baby's parents.

And I think that presents a major conflict with the standard we have in law that applies, at least in language, to all genetic information. And we have that standard. It's been in place for a long time.

(AA, pp. 72-74, 80-81 (emphasis added).)

The intent of the GPA was further clarified in the March 17, 2009 committee session, where Representative Emmer explained that MDH was supposed to destroy blood samples under current law. (AA, p. 163.) In response, Representative Thissen stated, "I think that the way the bill was originally drafted called on this to happen actually..." (AA, pp. 163-164.)

Appellants

On March 11, 2009, after seeing the MDH continue to proceed without obtaining consent, despite the ALJ rulings and Governor's veto, Appellants commenced this lawsuit. Appellants include 28 children and their parents/guardians. MDH collected blood specimens and performed newborn screening for each of the 28 children. (AA, p. 180.) MDH received two parental destruction directives (one for destruction of the specimen and test results, and the other only for destruction of the test results.) (AA, p. 180.) MDH alleges that it has not used any blood specimens from 26 of the children for public health studies or research. (AA, p. 181.) MDH cannot confirm whether or not specimens from the remaining two children were used in public health studies or research. (AA, p. 181.)

Appellants had disturbing experiences with newborn screening. For example, in two separate incidents, Appellant Andrea Kish-Bailey objected to the hospital's taking of her newborn children's blood, but the nurse told her, contrary to MDH's assertions, that the law mandated the sample. (AA, p. 12.) The nurse and hospital took samples from the two children despite their objections. (AA, p. 12.) Another Appellant, Shay Rohde, heard about MDH's conduct before the birth of her child and was prepared to object to the taking of the blood sample. (AA, p. 10.) Rohde indicates she never received any written documents or information about the reasons for the taking of the blood test at the hospital, such as the MDH pamphlet (AA, p. 10.) Rohde objected to the blood test but a pediatrician represented to Rohde that the blood sample was not used for a DNA test. (AA, pp. 10-11.) Rohde consented. Rohde later requested, in writing, the destruction of the blood spot and test data. (AA, p. 11.) Rohde never received a response to her request for destruction. (AA, p. 11.)

Appellants brought this lawsuit seeking damages and injunctive relief under statutory, constitutional, and common law. (AA, p. 9.) Respondents immediately moved for dismissal under Rule 12 or in the alternative for summary judgment. On November 24, 2009, the district court granted the motion. (AA, p. 268.) Appellants appealed.

STANDARD OF REVIEW
de novo

The district court dismissed the Amended Complaint under Rules 12.02 and 56. Under Rule 12, the court only determines whether the Complaint sets forth a legally sufficient claim for relief. *Nolan v. City of Eagan*, 673 N.W.2d 487, 492 (Minn. Ct. App. 2003) *review denied* March 16, 2004. The court accepts the facts in the Complaint as true and makes all reasonable and favorable inferences in favor of Appellants. *Id.* A motion to dismiss must be denied “if it is possible on any evidence which might be produced, consistent with the pleader’s theory, to grant the relief demanded.” *Id.* This court reviews dismissal under Rule 12.02 *de novo*. *Bahr v. Capella University*, 765 N.W.2d 428, 436 (Minn. Ct. App. 2009).

Under Rule 56, movants must prove there is no genuine issue of fact and that they are entitled to judgment as a matter of law. *Sauter v. Sauter*, 70 N.W.2d 351, 353 (Minn. 1955). “All doubts and factual inferences must be resolved against the moving party.” *Nord v. Herreid*, 305 N.W.2d 337, 339 (Minn. 1981) (emphasis added). “On appeal from a grant of summary judgment, this court reviews the record to determine whether there are any genuine issues of material fact and whether the lower courts erred in their application of the law.” *Art Goebel, Inc. v. North Suburban Agencies, Inc.*, 567 N.W.2d 511, 515 (Minn. 1997). Whether a genuine issue of material fact exists is reviewed *de novo* review. *Brookfield Trade Center, Inc. v. County of Ramsey*, 609 N.W.2d 868, 874 (Minn. 2000) *rehearing denied* May 23, 2000. The district court’s application of law is also reviewed *de novo*. *Art Goebel*, 567 N.W.2d at 515.

This appeal presents pure questions of law as to whether a cause of action exists to enjoin and remedy Respondents' unlawful collection, storage, use, and dissemination of Appellants' genetic material and test results. "No deference is given to a lower court on questions of law." *Modrow v. JP Foodservice, Inc.*, 646 N.W.2d 389, 393 (Minn. 2003).

ARGUMENT

A. Respondents violated Minn. Stat. § 13.386, the Genetic Privacy Act.

The GPA specifically addresses the dangers of government held DNA information and materials. It prohibits the collection, storage, use, and dissemination of “genetic information” without written, informed consent. Minn. Stat. § 13.386, subdiv. 3. The disputes on the statutory claim are legal in nature: (1) whether blood samples and test results are “genetic information” under the statute; (2) whether the newborn screening program trumps the statute’s privacy protections; (3) whether de-identification effects application of the statute; and (4) whether certain Appellants have standing to assert claims under the statute.

1. **Newborn blood specimens and newborn screening test results constitute genetic information under the Genetic Privacy Act.**

Respondents are responsible for two distinct violations of the GPA: (1) the storage, use, and dissemination of newborn *blood specimens* following initial newborn screening, and (2) the collection, storage, use, and dissemination of *test results* obtained through screening and other testing of the newborn blood specimens. The statute provides two definitions for “genetic information”:

- (a) “Genetic information” means information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of:
 - (1) the individual’s biological information or specimen; or
 - (2) the biological information or specimen of a person to whom the individual is related.
- (b) “Genetic information” also means medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or the individual’s family members.

Minn. Stat. § 13.386, subdiv. 1. Under these definitions, information obtained from testing of newborn blood samples and the blood samples are genetic information under the statute.

i. Newborn screening test results constitute genetic information under the statute.

Respondents do not dispute that the test results from newborn screening constitute genetic information. Newborn screening tests for congenital genetic conditions and the results are medical and biological information about a particular genetic condition. The information is used for the treatment of any individuals with positive test results and any test results, negative or positive, could be used for an individual's future medical treatment. Thus, genetic test results obtained from any testing (whether by Respondents or private organizations) fall within the scope of the Genetic Privacy Act.

ii. Newborn blood samples are genetic information under the statute.

Blood specimens are genetic information under the statute's plain language and proper statutory construction establish that the blood samples are genetic information under the statute. As a preliminary matter, even if the blood is not genetic information, its storage is nonetheless a constructive violation of the GPA.

Constructive Violation. First, Respondents are in constructive violation of the statute by possessing the blood samples, regardless of whether the samples are "genetic information." Only one purpose exists for the Department's warehousing of blood specimens - the future analysis and extraction of genetic information. While it may be possible to collect and store blood specimens, it is impossible to analyze them without obtaining "medical or biological information". Because there is no purpose for keeping

the specimen, except for further analysis and testing, storage of a specimen is constructive collection, storage, and use of genetic information as defined by the statute.

Plain Meaning. Second, the plain language of the statute establishes that blood samples are “genetic information.” The Merriam-Webster online dictionary defines “information” as follows:

- 2 a(1): knowledge obtained from investigation, study, or instruction...
- b: the attribute inherent in and communicated by one of two or more alternative sequences or arrangements of something (*as nucleotides in DNA* or binary digits in a computer program) that produce specific effects...

“Information.” Merriam-Webster Online Dictionary. 2009 Merriam-Webster Online. 21 September 2009. <<http://www.merriam-webster.com/dictionary/information>> (emphasis added). Under this common definition, the DNA within the blood sample is information because it contains arrangements/sequences of nucleotides. All that needs to be done is the translation of the information through testing and analysis.

Statutory Construction. Third, statutory construction establishes that the GPA applies to blood specimens. In district court, Respondents, in an effort to avoid the obvious meaning of the statute, strictly interpreted the word “information” to mean data obtained from study/testing of the newborn blood samples. If there is a dispute over the term, and an ambiguity in the statute, it requires resolution by statutory construction.

“The object of all interpretation and construction of laws is to ascertain and effectuate the intention of the legislature. Every law shall be construed, if possible, to give effect to all of its provisions.” Minn. Stat. § 645.16. When construing a statute, the court should be guided by the presumption that “(1) the legislature does not intend a

result that is absurd, impossible of execution or unreasonable” and “(2) the legislature intends the entire statute to be effective and certain.” Minn. Stat. § 645.17. When there are ambiguities in the law, the court should look to a number of factors in determining legislative intent, including: (1) the occasion and necessity for the law; (2) the circumstances under which it was enacted; (3) the mischief to be remedied; (4) the object to be attained; (5) the former law, if any, including other laws upon the same or similar subjects; (6) the consequences of a particular interpretation; (7) the contemporaneous legislative history; and (8) legislative and administrative interpretations of the statute. Minn. Stat. § 645.16. “[C]apricious distinctions are not to be imputed to the legislature. Unjust and indefensible results of a statute are to be avoided by construction, if possible.” *Pomeroy v. National City Co.*, 296 N.W 513, 515 (Minn. 1941). When the legislative intent of a statute is ascertained, it “must be so construed as to give effect to such intention, even if it seems contrary to... the strict letter of the statute.” *Winters v. City of Duluth*, 84 N.W. 788, 789 (Minn. 1901).

Respondents’ narrow view of “information” would yield an absurd result. Under Respondents’ interpretation, the statute would do nothing to prevent the indefinite, non-consensual storage of the most private characteristics of an individual – their DNA. This could not have been the intent of the legislature – especially given the comments made during the 2009 committee hearings.

Next, the legislative history supports the interpretation that blood specimens are included within the meaning of “genetic information.” The only contemporary history appears to be this exchange between legislators:

Representative Liebling:

Representative Holberg, I just have to ask you, the section that's in here on genetic information is that going to impact the Mayo Clinic's ability to do medical research, collect samples, and use it years later to cure diseases that we didn't even know that, that we had? I just wonder if you have been through the process with them and had hearing that in which you learned a little bit about how that might impact medical research in the state?

...

Representative Holberg:

Mr. Speaker and Representative Liebling, this governs the collection of data by government entities and does not preclude that collection if it's otherwise *allowed* by current law. This was a recommendation of the genetic study group. It was a bill of Representative Kahn's.

(AA, p. 261 (emphasis added).) Representative Holberg's statement makes it clear that Respondents' conduct had to be *expressly* authorized by law to avoid liability under the GPA. The only law in effect was the newborn screening statutes, which do not provide for the indefinite storage, use, and dissemination of genetic material and test results.

The legislature's intention may be further ascertained by considering administrative interpretations of the statute. Minn. Stat. § 645.16. The ALJ understood the absurdity of limiting the statute to test results. In her report, she recommended reforms to the proposed rules that required Respondents to inform parents who consented to use of genetic information to receive information regarding the future use of the test results *and* the blood sample. (AA, pp. 38-39.)

Lastly, the court must consider the consequences to the public of adopting Respondents' narrow view. Minn. Stat. § 645.16. If the Court adopts Respondents' narrow interpretation, it would hold that the indefinite storage, use, and dissemination of the unique genetic makeup of every child born in this state is not prohibited by statute. This renders the GPA meaningless. To give the statute any meaningful effect, blood samples must constitute genetic information.

2. The Genetic Privacy Act applies to conduct after initial newborn screening is complete.

Respondents attempt to circumvent the GPA by arguing the law does not apply to them, because of the directives of the newborn screening statutes. The district court erroneously agreed with their position. (AA, p. 276.) There is nothing in the newborn screening statute that permits the indefinite storage of test results and blood samples, the use of test results and samples beyond the newborn screening tests, or the dissemination of Minnesota children's test results and samples to private entities.

The GPA language restricts the non-consensual use of genetic information unless "*expressly provided by law...*" Minn. Stat. § 13.386, subdiv. 3 (emphasis added). The newborn screening statute provides that certain responsible parties are to collect the newborn blood specimens for testing and that the commissioner is responsible for determining which tests to administer. Minn. Stat. § 144.125, subdivs. 1-2. Another statute establishes the commissioner's duties concerning newborn screening. *See* Minn. Stat. § 144.128.

The only records that arguably could be kept under the newborn screening statutes are "a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of the follow-up services." Minn. Stat. § 144.128. This narrow provision does not authorize Respondents to keep a registry of cases for all testing results, nor does it authorize any storage of test results and blood samples beyond the immediate need for reporting to health care providers for follow-up care.³ The ALJ

³ Respondents also suggested that the newborn screening program is governed by pre-existing law found in Minn. Stat. §§ 13.02 (collection, security, and dissemination of records; definitions), 13.3805 (public health data). Neither of these statutes authorize

addressed this issue in detail, holding that the newborn screening statute did not authorize the indefinite retention and dissemination of the genetic information for purposes beyond the initial newborn screening. (AA, p. 28.) The Chief Administrative Law Judge agreed. (AA, pp. 56-57.)

Respondents argue that the GPA was not intended to change the newborn screening system. But Appellants do not contend that the GPA hinders the newborn screening program. Rather, the newborn screening program, when executed within its statutory limits, works harmoniously with the GPA's privacy protections. The GPA applies to the test results and samples when they are stored, used, and disseminated *beyond* the reporting of positive results for the purpose of follow-up care. The GPA allows newborn screening to proceed with the "opt-out system" but if Respondents wish to collect, store, use, and disseminate genetic information after the initial screening, they must adhere to the "opt-in" system and obtain informed consent pursuant to the GPA.

3. Respondents collected, stored, used, and disseminated Appellants' genetic information in violation of the Genetic Privacy Act.

In district court, Respondents' argued there were no violations because genetic information is de-identified. However, genuine issues of material fact exist as to whether disseminated information is de-identified. MDH admittedly collects, stores, and uses identified samples within its own system. And, in any event, dissemination of genetic material without informed written consent violates the statute - regardless of whether it is de-identified.

Respondents' illegal storage, use, and dissemination of genetic information beyond the immediate need for newborn screening and follow-up care.

i. Genuine issues of material fact exist as to whether disseminated genetic information is “de-identified.”

Under the first definition in the statute, “‘Genetic information’ means information about an identifiable individual...” Minn. Stat. § 13.386, subdiv. 1 (a). The statute does not define “identifiable individual.” See Minn. Stat. § 13.386. MDH has no standards for de-identifying samples or test results even when they are disseminated to third-parties. The evidence establishes that MDH’s process for de-identification vary and in fact would allow private parties, in some situations, to locate the sample donors and data subjects. Nonetheless, the district court erroneously held there was no dispute that the blood spots and test results were de-identified and therefore there was no violation of the statute. (AA, pp. 269-270.)

First, no blood sample is ever truly “de-identified.” It is common knowledge that DNA is unique to each human being. DNA is often referred to as a person’s “blueprint.” Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 Geo. Wash. L. Rev. 737, 773 (2004). Since DNA is a unique blueprint for each individual, it can never be fully de-identified.

Additionally, based on preliminary discovery in this matter there is evidence that Respondents disseminate blood samples and test results to private organizations with information that could lead to the identification of the specimen’s donor. Despite MDH’s reassurances that its dissemination is done with “de-identified” samples, it is not so clear what MDH means when they say that the blood samples and test data are “de-identified.” Respondents discovery responses stated, “No documents exist showing MDH processes

of de-identification and reidentification, nor is there any documentation about an “unidentified” standard or random identification keys. (AA, p. 131.)

Thus, it appears there are no set de-identification procedures and the process and standards for de-identification vary from project to project and are subject to subjective standards. For example, an e-mail exchange between MDH employees establishes that de-identification is a subjective standard. (AA, p. 132.) As the e-mail explains, the U of M cancer research center wished to use data from the cancer surveillance system, the birth registry, and newborn screening blood spots. MDH employees were to combine the data sources. (AA, p. 132.) The e-mail continues:

The only remotely identifiable information that the PI will receive is zip code from the MCSS (time of diagnosis), zip code from mother’s mailing address from the birth certificate, and the exact date of birth from both sources. The PI would not be able to use publicly available data sources to identify the child with these two data elements. (Although if he had access to our full birth certificate data base, *he could identify some children in sparsely populated zip codes.*)

(AA, p. 132 (emphasis added).) The MDH official had “No concerns.” (AA, p. 132.)

In another example, MDH intended to provide newborn blood specimens to a third-party research institution for “DNA extraction.” (AA, pp. 149-152.) According to the application, the specimens would “be assigned a random identification key, known only to the MDH Newborn Screening Program.” (AA, pp. 149-152.) Thus, MDH retains for its reference a “random identification key.” Should the need or desire arise, MDH could link results from private studies to the individual sample donors.

ii. *Violations occur, even if genetic information is “de-identified.”*

Under the second definition, “genetic information” means “medical or biological information collected from an individual...”. This definition does not include the

requirement that the information must be about an identifiable individual. Accordingly, even if the blood samples and test results are stored, used, or disseminated without identifying information, they are still subject to the requirements of written consent.

4. All Appellants are entitled to relief under the Genetic Privacy Act.

The GPA was effective as of August 1, 2006 and “applies to genetic information collected on or after that date.” 2006 Session Laws, Ch. 253 § 4. The district court held the GPA applied only to those children whose results were collected after August 1, 2006. (AA, p. 276.) However, the GPA applies to all the children because they still have claims for actual, constructive, and proposed violation of the GPA.

First, there is no dispute that testing performed on blood samples results in the retrieval of genetic information. Thus, even if children had samples collected before August 1, 2006, any testing performed on these samples on or after August 1, 2006 is the collection and use of “genetic information.” The children still have viable claims for the collection, use, and storage of new information collected after August 1, 2006.

Similarly, each act of dissemination of a test result or sample, occurring after August 1, 2006 is a new violation of the act. Respondents identified two children for whom they had no record indicating whether or not their specimens were used in public health studies or research. (AA, p. 181.) On remand, further discovery is warranted to see whether it can be ascertained whether these children’s blood samples were used in private testing following the GPA’s enactment date, why Respondents cannot account for the use or dissemination of blood samples in their control, and whether there are issues of spoliation. Even if these children’s samples were collected before August 1, 2006, they would have a claim for its unlawful dissemination after August 1, 2006.

Finally, because there is no reason for Respondents to store the blood samples and newborn screening test results for an indefinite period, other than to make further use or generate more test results, all Appellants have continuing claims, under section 13.08, for injunctive relief and to compel compliance with the GPA.

B. Respondents are liable for their unlawful taking of Appellants' genetic property without just compensation.

The Fifth Amendment to the United States Constitution provides that private property shall not be taken for public use, without just compensation.⁴ Under, Article 1, Section 13 of the Minnesota Constitution, "Private property shall not be taken, destroyed or damaged for public use without just compensation therefore, first paid or secured." Both clauses protect Appellants' right of property in their genetic material.

1. Appellants have a property interest in their blood and DNA.

Appellants urge the court to adopt a rule of law in which genetic material is property protected by the state and federal constitutions. The rule is supported by Minnesota's implicit recognition of a property right in genetic material in statute and case law, by the trend throughout the country of recognizing property rights in genetic material, and Respondents' own treatment of blood and DNA as property.

i. Minnesota law recognizes a property right in genetic material.

Liberty and property are broad and majestic terms. They are among the great (constitutional) concepts... purposely left to gather meaning from experience... (T)hey relate to the whole domain of social and economic fact, and the statesmen who founded this Nation knew too well that only stagnant society remains unchanged. For that reason... [t]he Court has also

⁴ This amendment is applicable to the states through the Fourteenth Amendment to the United States Constitution. *Phillips v. Washington Legal Foundation*, 118 S.Ct. 1925, 1930 (1998).

made clear that the property interested protected by procedural due process extend well beyond actual ownership of real estate, chattels, or money.

Board of Regents of State Colleges v. Roth, 92 S.Ct. 2701, 2706 (1972) (internal quotations and citations omitted). Property rights and interests may be created by “existing rules or understandings that stem from an independent source such as state law-rules or understandings that secure certain benefits and that support claims of entitlement to those benefits.” *Id.* at 2709. Reviewing a variety of statutes and case law in Minnesota leads to the conclusion that Minnesota law recognizes a property interest in genetic material.

The Court should first look to the GPA as implying a property interest in genetic material. Section 13.386’s requirement that blood specimens and DNA be collected, used, stored, and disseminated only with the individual’s informed written consent suggests that individuals have an interest in the disposition and use of their genetic material as if it were their own property.

Additionally, other Minnesota statutes grant individuals control over their body and bodily tissues. They allow the transfer of the right of control to others, as one would transfer rights of control over common personal property. For example, individuals have the right to make anatomical gifts. Minn. Stat. § 525A.05. Others retain the right to make anatomical gifts on behalf of a decedent. Minn. Stat. § 525A.09. Individuals have the right to “direct the preparation for, type, or place of that person’s final disposition...” Minn. Stat. § 149A.80, subdiv. 1. “The right to control the disposition of the remains of a deceased person... *vests* in” certain survivors. Minn. Stat. § 149A.80, subdiv. 2 (emphasis added). Patients have the right to participate in the planning of their health

care and the right to refuse care. Written, informed consent must be obtained prior to a patient's participation in experimental research and patients have the right to refuse participation in experimental research. Minn. Stat. § 144.651, subdvs. 10(a), 12, 13. Finally, statute allows individuals to decide whether to offer their blood for others' use. Minn. Stat. § 145.41. And, it is a common practice in this state for individuals to receive compensation for supplying blood plasma.

Minnesota case law also implies a property interest in genetic material. In the only case close to point, *Balkowitsch v. Minneapolis War Memorial Blood Bank, Inc.*, the state supreme court recognized that blood is a tangible good. 132 N.W.2d 805, 810-811 (Minn. 1965). The plaintiff asserted implied warranty claims against the blood bank for providing "impure" blood. *Id* at 806. The court held that the transaction was more like a service but explained, "The activities involved in the transfusion of whole blood... involve acts *common* to legal concepts of both a sale and a service." *Id.* at 810-811 (emphasis added). Thus, while blood transfusions may not be actionable in warranty, there is nonetheless a basis under Minnesota case law for viewing blood, or for that matter other genetic material (such as DNA), as a tangible, saleable good – or , more succinctly, property.

ii. Courts throughout the nation recognize a property interest in genetic material.

Minnesota is not alone in recognizing genetic material as property. Federal and state courts throughout the country are establishing property rights in human tissue and genetic material. In the federal courts, the sale of blood plasma is considered the sale of a product for the purposes of determining "income" under the tax code. *Margaret Cramer*

Green v. Commissioner of Internal Revenue, 74 T.C. 1229, 1234 (T.C. 1980). The tax court could not escape the similarity between blood and other raw materials:

The rarity of petitioner's blood made the processing and packaging of her blood plasma a profitable undertaking, just as it is profitable for other entrepreneurs to purchase hen's eggs, bee's honey, cow's milk, or sheep's wool for processing and distribution. Although we recognize the traditional sanctity of the human body, we can find no reason to legally distinguish the sale of these raw products of nature from the sale of petitioner's blood plasma. Even human hair, if of sufficient length and quality, may be sold for the production of hair pieces.

Id.

The trend is quite prevalent in state courts, especially as issues from genetic engineering to artificial reproduction become more prevalent. For example, in *Hecht v. Superior Court*, the court concluded that vials of cryogenically frozen sperm were properly part of a decedent's estate. 20 Cal.Rptr.2d 275, 283 (Cal. Ct. App. 1993) *review denied* Sept. 2, 1993. In *York v. Jones*, the court applied a bailment theory to possession of cryopreserved pre-zygotes where the parties had treated the pre-zygotes as property. 717 F. Supp. 421, 425-426 (E.D. Va. 1989). And in *Carter v. Inter-Faith Hospital of Queens*, New York departed from *Balkowitsch* and held that those who supply blood to hospitals, but are not involved in providing the transfusion service itself, may be liable under the UCC's warranty protections. 304 N.Y.S.2d 97 (N.Y. Spec. Term 1969).

The Court will no doubt note the infamous case of *Moore v. Regents of the University of California*, 249 Cal.Rptr. 494, 498 (Cal. Ct. App. 1998) *review granted* Nov. 10, 1988. As part of his treatment for hairy cell leukemia, Moore's spleen was removed. *Id.* Without Moore's knowledge or consent, Moore's unique cells were developed into a cell line capable of producing pharmaceutical products of "enormous

therapeutic and commercial value.” *Id.* Moore brought suit, including a claim for conversion. *Id.* The district court dismissed the conversion action for pleading deficiencies and because no cause of action for conversion existed for human tissues. *Id.* at 501-502.

The California intermediate appellate court reversed and found a property interest in bodily tissue:

[W]e have concluded that plaintiff’s allegation of a property right in his own tissue is sufficient as a matter of law. We have been cited to no legal authority, public policy, nor universally known facts of biological science concerning the particular tissues referred to in this pleading which compel a conclusion that this plaintiff cannot have a sufficient legal interest in his own bodily tissues amounting to personal property.

...

In our evaluation of the law of property, we consider the definition of the word property and cases and statutes involving such issues as the right of dominion over one’s own body; the disposition of bodies after death; cornea transplants from deceased person; and medical experimentation on live human subjects. ***We find nothing which negates, and much which supports, the conclusion that plaintiff had a property interest in his genetic material.***

...

The rights of dominion over one’s own body, and the interests one has therein, are recognized in many cases. These rights and interests are so akin to property interests that it would be a subterfuge to call them something else.

Id. at 503-505 (internal quotations and citations omitted; emphasis added). The court ultimately concluded that Moore’s spleen “was something over which [Moore] enjoyed the unrestricted right to use, control, and disposition” and therefore Moore had an actionable conversion claim. *Id.* at 505

The California Supreme Court reversed on public policy grounds. *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990) *rehearing denied* Aug.

30, 1990.⁵ There was a vigorous dissent. Importantly, the dissent used blood to explain precisely why genetic material is property:

With respect to the sale of human blood the matter is much simpler: there is in fact no prohibition against such sales... While many jurisdictions have classified the transfer of blood or other human tissue as a service rather than a sale, this position does not conflict with the notion that human tissue is property. The reason is plain: No state or Federal statute prohibits the sale of blood, plasma, semen, or other replenishing tissues if taken in nonvital amounts. Nevertheless, State laws usually characterize these paid transfers as the provision of services rather than the sale of a commodity... The primary legal reason for characterizing these transactions as involving services rather than goods is to avoid liability for contaminated blood products under either general product liability principles or the [UCC's] implied warranty provisions. The courts have repeatedly recognized that the foregoing is the real purpose of this harmless legal fiction. Thus... it is perfectly legal in this state for a person to sell his blood for transfusion or for any other indeed, such sales are commonplace, particularly in the market for plasma.

Id. at 185.

Despite dismissal of Moore's property claim, there appears to be a general consensus that the decision in fact recognizes a right to property in one's biological matter. *See e.g.* Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U. L. Rev. 359, 373-5 (2000) (*Moore* "paradoxically reinforces the image of the body as property in its partial and inconsistent invocation of property analysis."). The decision is also highly criticized. One commentator in particular has advocated, "that individuals' interests in their bodies should be protected as property interests because the body is the physical manifestation of the individual's unique personality and self identify." Michelle

⁵ The court went on to state, "we do not purport to hold that excised cells can never be property for any purpose whatsoever..." *Id.* at 160. Thus, *Moore* did not settle whether genetic material is considered legal property under California law.

Bourianoff Bray, *Personalizing Personalty: Toward a Property Right in Human Bodies*, 69 Tex. L. Rev. 209, 239-240 (1990).

iii. Respondents' assertion of a property interests in Appellants' genetic material estopps Respondents' from denying that blood and DNA are property.

In district court, Respondents argued that Appellants lack property interest in their blood and DNA. Respondents' position is curious given their own assertion of a property interest in the blood spots. Take, for example, the following statements from MDH official David Orren in an intradepartmental e-mail:

The blood spot itself is property...

When I discussed with Don Gemberling, he unequivocally stated that our isolates and specimens are property...

I don't believe these federal rules supersede MDH's property rights in the blood spots or in any state law that might eventually govern the blood spots.

(AA, pp. 127-128.)

In *Moore*, the intermediate appellate court pondered the "irony" of the defendants' position. 249 Cal.Rptr. at 507. The court could not reconcile defendants' assertion that Moore had no property right in his genetic material with the defendants' own assertion of a property interest in the genetic material for their commercial endeavors. *Id.* This court should not permit Respondents to assert property interests in Appellants' genetic material while at the same time asserting that no person has a property interest in their own blood or DNA.

2. Respondents unlawfully took Appellants' blood and DNA without just compensation.

After acquiring Appellants' blood sample and DNA, MDH stores them, uses them for its own purposes, and then disseminates them to private parties under lucrative contracts. There is no dispute – Respondents have not obtained consent for these activities and Respondents have not justly compensated Appellants.

Respondents' will argue blood samples are lawfully acquired and therefore do not require just compensation. In district court, Respondents cited *Bennis v. Michigan* and *Lukkason v. 1993 Chevrolet Extended Cab Pickup* for the proposition that any taking already authorized by statute does not require just compensation. These cases are not legally or factually applicable. Those cases involve forfeiture statutes and “an exercise of the state's police power in the protection of public safety.” *Bennis*, 116 S. Ct. 994, 997-998 (1996) *rehearing denied* April 22, 1996; *Lukkason*, 590 N.W.2d 803, 807 (Minn. Ct. App. 1999) *review denied* May 18, 1999. But even if we assume Respondents' legal contention is correct, that the legislature may simply enact a statute or an agency adopt a rule for the taking of property to avoid the state's obligation to pay for takings, Respondents failed to show that their taking of the blood and DNA was lawful under any existing law. Here, there is no authority for the taking other than for the limited purpose of newborn screening. Any activities beyond the newborn screening are unauthorized.

C. Respondents are liable in tort for their unlawful conduct.

The district court dismissed the common law claims as “moot.” (AA, p. 277.) A careful review of authorities, however, establishes a solid basis for each claim.

1. Appellants stated claims for conversion and trespass to personalty.

Appellants brought claims for trespass and conversion. (AA, p. 6.) As discussed thoroughly in the government takings section of this brief, Appellants have a property interest in their blood and DNA. Respondents' violation of this property interest gives rise to a claim for conversion and trespass.

2. Appellants stated claims for negligence.

Respondents did not destroy blood samples and test results following screening. Respondents did not obtain consent for their post-screening activities. Respondents breached their duty, found in common law and statute, to protect Appellants privacy and bodily integrity.

First, Respondents owed Appellants a common law duty to respect and protect their privacy and bodily integrity. A common law duty is established when one voluntarily undertakes an affirmative duty. *Walsh v. Pagra Air Taxi, Inc.*, 282 N.W.2d 567, 570 (Minn. 1979). By collecting blood samples and DNA under the guise of newborn screening, Respondents undertook an affirmative duty to protect the privacy interests of those who provide the samples or may have private genetic information revealed by analysis of those samples:

To varying degrees, the entity receiving the genetic information owes various affirmative duties of care to the individual disclosing the information. Given the strong personhood interest in the information and the personal trust element of these relationships, the disclosure of this information is a kind of entrustment, obligating the receiver of the information to act with care with respect to the information.

Suter, *Understanding Genetic Privacy*, at 797.

Second, the GPA imposes a statutory duty on Respondents to get written informed consent for any storage, use, or dissemination of genetic material or test results. *See* Minn. Stat. § 13.386. If there is no consent, the statute is silent on what Respondents are to do, but the logical conclusion, derived from the statute's intent to protect privacy interests, is to destroy the genetic material and test results. Thus, absent that consent, the statute creates an implied duty to destroy the blood samples and test results for those who test negative for congenital disorders. Because the duty imposed on Respondents is statutory in nature, Appellants are essentially bringing a claim for negligence per se. *See Anderson v. State*, 693 N.W.2d 181, 189-190 (Minn. 2005). There is no dispute that Appellants are persons protected by the GPA. The minor children are protected from the storage of their blood samples. The parents have independent claims as well because the children's genetic makeup is revealing of the parent's genetic makeup. By requiring informed, written consent, the legislature intended to protect these individuals from the misuse of their private genetic information. And any departure from the standard of care imposed by the GPA subjects Respondents to negligence liability.

3. Appellants stated claims for intrusion upon seclusion.

Minnesota recognizes a cause of action for invasion of privacy called intrusion upon seclusion. *Elli Lake v. Wal-Mart Stores, Inc.*, 582 N.W.2d 231, 233, 235 (Minn. 1998). "The tort has three elements: (a) an intrusion; (b) that is highly offensive; (c) into some matter in which a person has a legitimate expectation of privacy." *Swarthout v. Mutual Service Life Ins. Co.*, 632 N.W.2d 741, 744 (Minn. Ct. App. 2001). An intrusion may occur through varying forms of "investigation or examination into [a plaintiff's] private concerns, as by opening his private and personal mail, searching his safe or his

wallet, examining his private bank account, or compelling him by a forged court order to permit an inspection his personal documents.” Restatement (Second) of Torts, 652B, cmnt. B. There is no publication requirement: “[t]he intrusion itself makes the defendant subject to liability...” *Id.*

A person’s genetic makeup is a highly private matter. Intruding into someone’s genetic code is a more serious violation of privacy and seclusion than any of the examples cited in the Restatement (Second) of Torts. “[O]ur privacy interests tend to encompass genetic information that is generally hidden and unknowable without some genetic analysis, such as disease susceptibility and reproductive risks.” Suter, *Understanding Genetic Privacy*, at 777. “Genetic information that is not easily known is often the sort of information we do not disclose widely.” *Id.* at 779. As discussed in the constitutional violation section of this brief, the Minnesota Supreme Court and the U.S. Supreme Court have recognized a reasonable expectation of privacy in one’s biological tissue and DNA.

By performing unauthorized testing and analysis of newborn blood samples, and disseminating samples and testing results to private parties for their own testing, Respondents intrude into highly sensitive and private information. This intrusion is highly offensive to any reasonable person. That is why intrusion upon seclusion should extend to the unlawful storage and analysis of genetic material.

4. Appellants stated claims for negligent infliction of emotional distress

Appellants also brought a claim for negligent infliction of emotional distress. (AA, p. 6.) Generally, a “plaintiff may recover for negligent infliction of emotional distress when that plaintiff is within a zone of danger...” *Bohdan v. Alltool Mfg. Co.*, 411

N.W.2d 902, 907 (Minn. Ct. App. 1987) *review denied* Nov. 13, 1987. However, “[a]n exception to the “zone of danger” rule is that a plaintiff may recover damages for mental anguish or suffering for a direct invasion of his rights...” *Id.* Under this “independent tort exception,” there is no requirement that a plaintiff provide evidence of severe distress and associated physical symptoms. *See id.* The plaintiff need only suffer “mental anguish or suffering.” *Id.* Thus, where a plaintiff may recover on an independent tort invading personal rights, and intentional tort, or some other tort involving willful, wanton, or malicious conduct, that plaintiff may at the same time maintain an action for negligent infliction of emotional distress. *See id.*

Here, Appellants have claims for the intentional torts of trespass to personalty and conversion. They also claim a direct invasion of the right to privacy in the tort and constitutional sense. So long as one of these claims is viable, Appellants are entitled to proceed on their claim for negligent infliction of emotional distress.

5. Appellants have viable claims for fraud and misrepresentation.

Appellants brought claims for fraud and misrepresentation because Respondents falsely represented through the nurses, physicians, and other responsible parties that the samples would be used solely for the newborn screening program and Respondents omitted the blood would be indefinitely retained, disseminated, and used in unauthorized genetic testing. (AA, pp. 6-7.)

Respondents’ most pervasive fraudulent misrepresentations occurred when Respondents provided Appellants with literature regarding newborn screening. (*See* AA, 217-226.) While this literature purports to notify parents of additional testing, it

fraudulently misrepresents that parents “must” opt-out of post-newborn screening testing, when in fact, the GPA provides that parents must opt-in.

Second, Respondents’ agents are not providing full disclosure to parents. Through their rule making authority, Respondents direct “responsible persons” to collect the blood samples and make certain representations concerning storage, use, and dissemination of the samples. *See* Minn. Admin. R. 4615.0500. The ALJ found that the “responsible parties” are MDH’s agents: “The proposed rules demonstrate that hospitals are merely acting, for a very brief period of time, as agents of the Department in carrying out the newborn screening program. ...” (AA, p. 35.) Indeed, one who authorizes an agent to make a tortious representation is liable for the representation made by that agent. *Opatz v. John G. Kinnard and Co., Inc.*, 454 N.W.2d 471, 474 (Minn. Ct. App. 1990) (“A principal who puts a servant or other agent in a position which enables the agent, while apparently acting within his authority, to commit a fraud upon third persons is subject to liability to such third persons for the fraud.”).

There are genuine issues of material fact concerning these misrepresentations. For example, Appellant Shay Rohde, heard about MDH’s conduct before the birth of her child and was prepared to object to the taking of the blood sample. (AA, p. 10.) Rohde never received any written documents or information about the reasons for the taking of the blood test at the hospital. (AA, p. 10.) Rohde objected to the blood test but a pediatrician later represented to Rohde that the blood sample was not a DNA test. (AA, pp. 10-11.) Rohde later requested, in writing, the destruction of the blood spot and test data. (AA, p. 11.) Rohde never received a response to her request. (AA, p. 11.) In this particular instance, Respondents’ agents misrepresented the nature of testing that will be

done on the blood sample (as MDH and private entities perform DNA testing) and misrepresented that Rohde would be able to request the timely destruction of the blood sample.

D. Respondents violated Appellants' fundamental rights to privacy and bodily integrity under the Minnesota and United States Constitutions.

Appellants brought claims for violation of their right to privacy under the Minnesota and U.S. Constitutions. (AA, pp. 7-8.) Additionally, Appellants brought direct claims for damages under the Minnesota Constitution. The district court refused to analyze the constitutional claims and simply dismissed them as "moot." (AA, p. 277.)

- 1. Respondents unlawfully searched Appellants through the collection, storage, and use of their blood spots and DNA without informed consent; Respondents' ongoing storage, use, and dissemination of Appellants' genetic material are continuing violations of Appellants' rights to privacy and bodily integrity.**

Respondents' collection, use, storage, and dissemination of Appellants' genetic material, beyond the initial need for newborn screening, violated Appellants' constitutional right to privacy.

i. The United States Constitution protects Appellants' genetic privacy.

The United States Constitution provides that the "right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated..."⁶ U.S. Const., Amend. IV. To the extent that certain rights are not specifically enumerated, the U.S. Constitution provides that additional fundamental rights are reserved for the people. U.S. Const., Amend. X ("The enumeration in the

⁶ Protections under the Fourth Amendment to the United States Constitution are applicable to the states through the Fourteenth Amendment. *Terry v. Ohio*, 88 S.Ct. 1868, 1873 (1968).

Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.”).

Over forty years ago, in *Schmerber v. State of California*, the U.S. Supreme Court held that collection and analysis of blood samples is a search under the Fourth Amendment. 86 S. Ct. 1826 (1966). According to the court, “The overriding function of the Fourth Amendment is to protect personal privacy and dignity against unwarranted intrusion by the State.” 86 S. Ct. at 1834. The court recognized a heightened privacy interest when it comes to government intrusions into the human body. *Id.* at 1835.

Over twenty years later, the court further confirmed that analysis of biological material is an intrusion of the right to privacy:

We have long recognized that compelled intrusion into the body for blood to be analyzed for alcohol conduct must be deemed a Fourth Amendment Search. In light of our society’s concern for the security of one’s person, it is obvious that this physical intrusion, penetrating beneath the skin, infringes an expectation of privacy that society is prepared to recognize as reasonable. *The ensuing chemical analysis of the sample to obtain physiological data is a further invasion of the [individual’s] privacy interests.*”

Skinner v. Railway Labor Executives’ Association, 109 S. Ct. 1402,1412-1413 (1989)
(emphasis added).

More recently, in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, the Ninth Circuit Court of Appeals held that unauthorized testing and analysis of blood samples was unconstitutional. 135 F.3d 1260, 1268-1270 (9th Cir. 1998). According to the court:

The constitutionally protected privacy interest in avoiding disclosure of personal matters clearly encompasses medical information and its confidentiality.

...

[I]t goes without saying that the *most basic* violation possible involves the performance of unauthorized tests—that is, the non-consensual retrieval of

previously unrevealed medical information that may be unknown even to plaintiffs.

...
One can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up.

Id. at 1269 (emphasis in original).

ii. Minnesota's constitution protects Appellants' genetic privacy.

The Minnesota Constitution provides that the "right of the people to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures shall not be violated... Minn. Const., Art. 1 § 10. The constitution further provides that "[t]he enumeration of rights in this constitution shall not deny or impair others retained by and inherent in the people." Minn. Const., Art. 1 § 16.

The Minnesota Supreme Court recognized the right of privacy under the Minnesota Constitution over twenty years ago:

A comparison of the Minnesota Bill of Rights with the federal constitutional provisions upon which the right of privacy is founded shows that the rights protected by the Federal Constitution are also protected by the Minnesota Bill of Rights. Accordingly, it is our opinion that there does exist a right of privacy guaranteed under and protected by the Minnesota Bill of Rights.

State v. Gray, 413 N.W.2d 107, 110 (Minn. 1987).

There is a right to privacy under the Constitution of Minnesota. The right begins with protecting the integrity of one's own body and includes the right not to have it altered or invaded without consent.⁷

⁷ The Minnesota Constitution provides greater privacy protection than the U.S. Constitution. The Minnesota supreme court has "frequently recognized that privacy rights are more broadly defined under the Minnesota Constitution than under the United States Constitution." *State v. Jordan*, 742 N.W.2d 149, 159 (Minn. 2007) (Meyer, J. concurring). Indeed, the Minnesota Constitution provides greater protection than the Fourth Amendment. *State v. Askersooth*, 681 N.W.2d 353, 362 (Minn. 2004). Thus, if the U.S. Constitutional claims are rejected, the Court must analyze the Minnesota constitutional claims independently.

Jarvis v. Levine, 418 N.W.2d 139, 148 (Minn. 1988) *rehearing denied* Aug. 22, 1988.

Recently, in *Welfare of C.T.L.*, the court of appeals considered the constitutionality of a statute allowing law enforcement to take a biological specimen from a person charged with, but not convicted of, an offense. 722 N.W.2d 484, 491 (Minn. Ct. App. 2006). The court carefully considered *Schmerber* and agreed that individuals have a heightened privacy interest in their body. *Id.* The Minnesota Supreme Court held the statute unconstitutional - effectively requiring that a judicial determination of probable cause (or exigent circumstances) must exist before biological specimens are taken or analyzed from someone not convicted of an offense. *Id.* at 492.

iii. Respondents have no interest in the collection, storage, use, and dissemination of Appellants' blood samples and test results without consent.

Respondents' conduct is unconstitutional if Appellants' privacy interests outweigh Respondents' interest in the collection, storage, use, and dissemination of Appellants' blood samples, DNA, and genetic test results without consent. *Norman-Bloodsaw*, 135 F.3d at 1269; *Kremin v. Graham*, 318 N.W.2d 853, 855 (Minn. 1982). The federal balancing test requires considering the degree of intrusiveness, the state's interests in requiring the intrusion, and the "efficacy" of the state's means for meeting its needs. *Norman-Bloodsaw*, 135 F.3d at 1269. Similarly, the balancing test under Minnesota's constitution examines "(1) the importance of the state's purpose in requiring the intrusion in question, (2) the nature and seriousness of the intrusion, (3) whether the state's purpose justifies the intrusion, and (4) whether the means adopted is proper and reasonable." *Kremin*, 318 N.W.2d at 856, n. 5.

No Compelling Interest. Two cases in particular illustrate that government has no interest in obtaining genetic material from innocent citizens without consent. First, in *Norman-Bloodsaw*, the defendants (as government actors) required that plaintiffs consent to a pre-employment health evaluation. 135 F.3d at 1264-1265. As part of the evaluation, the plaintiffs provided answers to a health questionnaire and provided blood and urine samples. *Id.* at 1265. The blood and urine were tested for syphilis, pregnancy, and sickle cell trait. *Id.* at 1269-1270. The court held that consent to a general medical testing, filling out a questionnaire, or giving a blood or urine sample “does not abolish one’s privacy right not to be tested for intimate, personal matters involving one’s health...” *Id.* Moreover, “if unauthorized, the testing constituted a significant invasion of a right that is of great importance, and labeling it minimal cannot and does not make it so.” *Id.*

Second, in *Welfare of C.T.L.*, the Minnesota Supreme Court concluded that privacy interests outweigh any state interest in establishing DNA databases (even for the criminally *accused*). The court concluded the BCA’s requirement that the State destroy the biological specimen and remove information about the specimen from the state’s DNA index upon dismissal of charges “suggests that the legislature has determined that the state’s interest in collecting and storing DNA samples is outweighed by the privacy interest of a person who has not been convicted.” 722 N.W.2d at 491.

Under long standing constitution principles, the state is prohibited from intruding into its citizens private medical matters through the analysis blood and DNA that is being stored without consent. It has no interest in maintaining a DNA database of innocent

citizens. The express genetic privacy protections afforded by the Genetic Privacy Act are in accord with the reasoning of *Norman-Bloodsaw* and *Welfare of C.T.L.*

Granted, there are cases in which the state may have a limited interest in collecting genetic material and maintaining DNA databases. For example, in *Schmerber*, while emphasizing that the taking and analysis of blood samples is a search under the Fourth Amendment, the court held, on the facts of that particular record that a police officer reasonably believing that he was confronted with an emergency and delay in obtaining the warrant threatened the destruction of evidence, was constitutionally permitted to obtain a blood sample to determine blood alcohol content. 86 S.Ct. at 1834, 1836-1837. In *Kremin*, the court held that a statute requiring blood testing from a putative father for the purpose of determining paternity was constitutional. 318 N.W.2d at 855-856.

The results in *Shmerber* and *Kremin* have no application here. To begin with, the interests involved are entirely different. In *Schmerber*, the intrusion occurred in the context of a criminal investigation and exigent circumstances. 86 S.Ct. at 1829. In *Kremin*, the tests were done to establish paternity. 318 N.W.2d at 854. Neither case involves the analysis of DNA of innocent newborn children where the government had ample opportunity to obtain informed, written consent. Another key distinguishing factor is the limited scope of testing. In *Schmerber*, the government tested only for the presence of alcohol. 86 S.Ct. at 1829. In *Kremin*, the government tested only for a paternity match. 318 N.W.2d at 854. In those cases, the government did not test for genetic disorders and other private medical factors. However, the government testing in *Norman-Bloodsaw* went beyond superficial testing and sought personal medical

information. That severe intrusion was unconstitutional.⁸ When analysis of biological samples delves in a citizen's genetic makeup, the intrusion becomes particularly heinous.

Privacy Interests Outweigh State Interests. Assuming the state successfully argues that its use of genetic materials and data beyond newborn screening serves a public health interest, that purported interest does not outweigh genetic privacy. As explained in *In re C.T.L.*, the state's interest in keeping the samples for alleged criminals is outweighed by privacy interests. Privacy interests outweigh to an even greater degree, any state interest in storing, using, and disseminating, without consent, newborn blood samples, DNA, and test results. The genetic privacy of every child in this state should not be sacrificed in the name of "public health."

Poorly Tailored. But even if Respondents purported interest in public health outweighs Appellants privacy rights, Respondents conduct still fails constitutional scrutiny because the post-newborn screening activities are not sufficiently tailored to meet the states interest while balancing privacy concerns. Quietly retaining blood samples taken for newborn screening, then storing the samples, further analyzing the DNA and collecting test data, and then disseminating the samples, DNA, and test data to private parties is the worst tailored approach. The only reasonable approach to Respondents' practice is to obtain written, informed consent, as provided by the GPA. This avoids unwelcome intrusions and promotes education about the scope and purpose of the intrusion.

⁸ It is worth noting that in *Schmerber*, the court emphasized: "The integrity of an individual's person is a cherished value of our society. That we today hold that the Constitution does not forbid the States minor intrusions into an individual's body under stringently limited conditions in no way indicates that it permits more substantial intrusions, or intrusions under other conditions." 86 S.Ct. at 1836.

Furthermore, there is no authority establishing that Respondents may invade the human body, take a blood sample, and perform tests on the blood sample simply because victims may, *after the intrusion*, opt-out and have the sample and test results destroyed. Rather, in the absence of suspected criminal activity, Respondents must obtain consent *before* the intrusion. An opt-out system does not respect rights; it facilitates and enables their violation. The U.S. and Minnesota constitutions are designed to *prevent* the initial intrusion. They impose a duty on Respondents to respect Appellants' rights, not establish a system that requires Appellants to suffer an intrusion and then take corrective action.

2. Appellants have a cause of action for damages against Respondents for violation of Minnesota's constitution.

For violation of the United States Constitution, Appellants may seek damages under 42 USC § 1983. Appellants also seek damages for violation of Minnesota's constitution.

"[T]he Minnesota Supreme Court and Minnesota Court of Appeals have assumed that plaintiffs may bring a private action to enforce the Minnesota Constitution." John M. Baker, *The Minnesota Constitution as a Sword: The Evolving Private Cause of Action*, 20 Wm. Mitchell L. Rev. 313, 316 (1994). Minnesota's constitution provides:

Every person is entitled to a certain remedy in the laws for all injuries or wrongs which he may receive to his person, property or character, and to obtain justice freely and without purchase, completely and without denial, promptly and without delay, conformable to the laws.

Minn. Const., Art. 1 § 8. "These words were not inserted in the constitution as a matter of idle ceremony, or as a string of glittering generalities and must be respected even by public officers." *Thiede v. Town of Scandia Valley*, 14 N.W.2d 400, 408 (Minn. 1944) (internal quotations and citation omitted).

At least three cases recognize a private cause of action for damages based on violations of Minnesota's constitution. In *Thiede*, the supreme court held town officials personally liable for an eviction that violated a plaintiff's right to property under Minnesota's constitution. *Id.* at 406-408. The court relied on Article 1 Section 8 as a basis for allowing damages actions for violation of the plaintiff's right to property. *Id.* at 408. In *Wegner v. Milwaukee Mutual Ins. Co.*, the court upheld a private cause of action for damages under the takings clause of Minnesota's constitution when police damaged a private residence in hot pursuit of narcotics dealers. 479 N.W.2d 38, 40-42 (Minn. 1991) *rehearing denied* Jan. 27, 1992. The claims were not brought under an inverse condemnation statute. *Id.* Similarly, in *McGovern v. City of Minneapolis*, claims proceeded for damages under the takings clause of Minnesota's constitution for damages occurring during police raids of a drug house. 480 N.W.2d 121, 126-127 (Minn. Ct. App. 1992) *review denied* Feb. 27, 1992. According to one commentator, "the Minnesota Supreme Court and Court of Appeals treated the availability of a private cause of action in *Wegner* and *McGovern* as a foregone conclusion." Baker, *Minnesota Constitution as a Sword*, at 318-19.

Nonetheless, in district court, Respondents asserted sovereign immunity barred Appellants' damages claim for constitutional violations. But the supreme court explicitly abolished the doctrine of sovereign immunity, at least as applied to tort claims. *Nieting v. Blondell*, 235 N.W.2d 597, 601-603 (Minn. 1975) *rehearing denied* Dec. 12, 1975. The supreme court recognized the inequity of sovereign immunity: "The question of the fairness of the doctrine of sovereign immunity has been presented to us previously, and we have found it wanting." *Id.* at 601. The court concluded that the rule survived by

“accident” and only continued due to judicial “inertia.” *Id.* The court found no compelling reasons to continue recognizing the doctrine, found the doctrine no longer served a useful purpose, and abandoned it. *Id.* at 601, 603. Abolishing sovereign immunity as applied to constitutional violations is the logical and necessary extension of *Nieting*.

Respondents may rely on *Mitchell v. Steffen*, 487 N.W.2d 896 (Minn. Ct. App. 1992) review granted Aug. 4, 1992, for the proposition that damage claims under Minnesota’s constitution are barred by sovereign immunity. There, a claim was brought for violation of Minnesota’s equal protection clause by a statute that provided reduced welfare benefits to those whom were residents in the state for less than six months. *Id.* at 899. The court of appeals concluded that the claims for equal protection did not seek money damages but rather sought equitable relief in the form of specific performance. *Id.* at 907. In dicta, the court of appeals speculated that if the claim was for damages for violation of the equal protection clause would be barred by sovereign immunity. *Id.* at 906.

Upon further review, the supreme court declined to address the state constitutional questions. *Mitchell v. Steffen*, 504 N.W.2d 198, 203 (Minn. 1993) (There is no need to consider whether the 1991 amendment violates our state equal protection clause, and we do not reach that issue.) Because the statements in the court of appeals decision in *Mitchell* are dicta and indeed contradict prior holdings by Minnesota’s supreme court, the case is not authoritative on the private cause of action for damages. The Court should return to the holdings in *Thiede*, *Wegner*, and *McGovern* and recognize that Appellants

have a private cause of action against Respondents for unlawfully taking, storing, using, and disseminating their genetic material.

CONCLUSION

Appellants respectfully request that the district court order granting Respondents' motion to dismiss and for summary judgment be *reversed* in its entirety and this case be remanded for further discovery and trial.

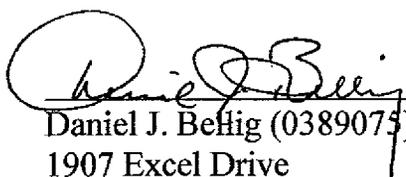
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CASE NO. A10-101

STATE OF MINNESOTA

IN COURT OF APPEALS

Alan and Keri Bearder, individually and as parents and
natural guardians of Josiah and Alexa Bearder, minors; et al.,

Appellants,

vs.

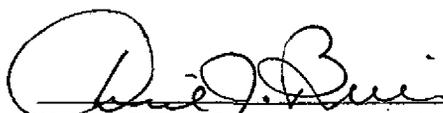
State of Minnesota,
Minnesota Department of Health, and
Dr. Sanne Magnan, Commissioner
of the Minnesota Department of Health,

Respondents.

CERTIFICATION OF BRIEF LENGTH

I hereby certify that this brief conforms to the requirements of Minn. R. Civ. App.
P. 132.01, Subds. 1 and 3, for a brief produced with a proportional font. The length of
this brief is 13,892 words. This brief was prepared using Microsoft Office Word 2003.

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